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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,941	NIR ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-163* is/are pending in the application.

4a) Of the above claim(s) *86-149* is/are withdrawn from consideration.

5)☐ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-85 and 150-163* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/13/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RJ

DETAILED ACTION

Claims 1-163 are pending. Claims 86-149 are withdrawn from consideration as they are drawn to non-elected invention. Claims 1-85, and 150-163 are examined herein.

Election/Restrictions

Applicant's election without traverse of Group I claims 1-85, and 150-163, drawn to a composition-of-matter comprising a polymer and an oxidizing agent, the method of treating a skin ailment using the said composition and method of preparing the said composition filed on 10/29/2004 is acknowledged. The restriction requirement is made FINAL.

Claim Objections

Claim 162 is objected to because of the following informalities:

The word "proceeds" should be "precedes".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 159, and 160 is rejected under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 159 recites "polymerizing a second silicone polymer so as to obtain a second polymerized silicone polymer" is not clear, as to whether the Applicant mean to say that polymerizing a second silicone polymer so as to obtain a cross-linked second silicone polymer.

The claim 160 recites "polymerizing a silicone polymer so as to form a polymerized silicone polymer" is not clear, as to whether the Applicant mean to say that polymerizing a silicone polymer so as to form a cross-linked silicone polymer.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-85, and 150-157 are rejected under 35 U.S.C.112, first paragraph, because the specification, while being enabling for skin ailment such as warts, **does not reasonably provide enablement for all skin or mucosal membrane ailments**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when

assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

The rejected claims are drawn to an invention, which pertains to a method of treating skin or mucosal membrane ailment, comprising applying onto a treated region of the skin an oxidizing agent entrapped in or by a polymer.

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a **method of treating any or all skin or mucosal membrane ailments**.

(3). Guidance of the Specification / (4). Working Examples:

In the instant case, only working examples that are presented in the specification as filed show a **method of treating skin ailment such as warts**.

The guidance given by the specification as to what types of skin or mucosal membrane ailments can be treated with the instant composition is limited to skin ailments caused by Human papilloma virus, and bacteria such as *Staphylocccus aureus*, *Streptococcus agalactiae* IMI.

(5). State of the Art / Predictability of the Art:

The relative skill of those in the art is high.

The invention is directed to a method of treating skin or mucosal membrane ailment comprising applying to skin an oxidizing agent entrapped in a polymer. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use **for treating any or all skin or mucosal ailments** using the instant pharmaceutical compositions. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the **scope of enablement** varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839 (1970). The skin ailments claimed in the instant invention will have different etiologies (See The Merck Manual, Fifteenth Edition, pages 2247-2276). For examples skin ailment such as Contact Dermatitis may be caused by a primary chemical irritant, soap, acids, alkalis etc. or may be a Type IV delayed hypersensitive reaction due to contact with poison ivy, oak etc. Moreover many skin diseases such as psoriasis (cause is unknown) and skin cancers are very difficult to treat, despite the fact that there are many drugs, which can be used for "inflammatory condition". No one composition has been found to treat skin ailments of all types generally. Hence the instant claims read on the employment of compositions comprising oxidizing agents entrapped in polymer matrix in **treating any skin or mucosal ailments**, necessitating one of skill in the art to perform an exhaustive search for the embodiments herein suitable to practice the claimed invention.

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of ordinary skill in the art would have to first envision a pharmaceutical composition, a dosage for each oxidizing agent, the duration of treatment, route of treatment etc. One would then need to test the compositions in the model system to determine whether or not the composition is effective in treating the desired skin ailment. One would then also need to test the composition in the model system for side effects and toxicity. Thus a person of skill in the art would have to engage in **undue experimentation** to test all compositions encompassed in the instant claims to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10-14, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Amer et al. (US 4,759,956, PTO-892).

The instant claims are directed toward a composition-of-matter comprising a polymer and an oxidizing agent entrapped in or by said polymer.

Amer et al. disclose a detergent composition comprising solid particles, of oxidizing agents encapsulated with polymers. See column 2, lines 56-60; column 5, lines 53-55. A wide variety of polymers which are conformable, flexible, and spreadable such as styrene, acrylic copolymers are disclosed. See column 4, lines 49-column 5, line 5; column 3, lines 7-10. The polymer forms a film over the solid active core. See column 4, lines 49-column 5, line 5; column 3, lines 7-10. The polymer coating can be applied from an aqueous solution. See column 2, lines 32-34. The solid particles that are entrapped in the polymer are oxidizing agents, wherein the oxidizing agent has oxidizing properties per se a peroxygen compound, a chlorine releasing agents such as calcium hypochlorite, an agent which is hydrolysable into an oxidizing moiety such as sodium dichloroisocyanurate (which reacts with water to produce oxidizing agent hypochlorous acid, which is source of free chlorine) present in amounts 1 % to 99 % are disclosed. See column 5, lines 6-8, lines 48-50, and lines 63-65.

Therefore, Amer et al. anticipate claims 1-5, 10-14, and 25.

Claims 150-156, are rejected under 35 U.S.C. 102(b) as being anticipated by Boddie et al. (J. Dairy.Sci. 79, 1996, pages 1683-1688, of record in PTO-1449).

The instant claims are directed to a method for the treatment of skin ailment comprising applying onto a treated region of skin an oxidizing agent, which is hydrolizable into oxidizing moiety having oxidizing properties.

Boddie et al. discloses a method of treating teat skin infected by microorganism wherein the microorganism is bacteria such as *Staphylococcus*, *Streptococcus agalactiae* by dipping teats in the formulation containing 4 % by weight of oxidizing agent sodium hypochlorite. See page 1683, abstract, and INTRODUCTION. Boddie further discloses teat dip formulations containing an oxidizing agent hypochlorous acid (a source of free chlorine) which was liberated from sodium dichloroisocyanurate in water by hydrolysis, that were effective against bacteria such as *Staphylococcus aureus* and *Streptococcus agalactiae* IMI. See page 1683, column 2, lines 24-29.

Therefore, Boddie et al. anticipate claims 150-156.

Claims 26, 35-38, 57, 66-68, 150, and 155-157 are rejected under 35 U.S.C. 102(b) as being anticipated by Danner et al. (US 5,855,922, PTO-892).

The instant claims are directed toward Pharmaceutical composition, and a method for the treatment of skin ailment caused by human papilloma virus comprising a polymer and an oxidizing agent entrapped in or by said polymer.

Danner discloses an antimicrobial composition comprising an oxidizing agent an aqueous solution of metal chlorate for the treatment of dermal disorders

caused by viruses such as papilloma viruses, yeasts, bacteria, fungi. See column 5, lines 57-65; column 1, lines 59-63; column 6, line 48. Danner also teaches that the compositions may be applied to human or animal skin in conjunction with gel application medium wherein the gels can be biocompatible polymers such as Cellulose gels, polyvinylsulfonic acid, polyamide or silica base gels. See column 6, lines 58-65.

Therefore, Danner anticipates claims 26, 35-38, 57, 66-68, 150, and 155-157.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 9-11, 26-30, 34-37, 39-40, 57-61, 65-67, and 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Karagoezian (US 6,592,907, PTO-892).

The instant claims are directed toward a Pharmaceutical composition comprising an oxidizing agent being entrapped in a sustained-release polymer, and a method of treating skin or mucosal membrane ailment using said composition.

Karagoezian discloses medical compositions and methods for the antimicrobial preparation to treat dermatological disorders (i.e skin or mucous membrane) such as wounds, ulcers, psoriasis, acne and other lesions. See column 1, lines 11-20. The antimicrobial preparations comprise oxidizing agent such as hydrogen peroxide/metal chlorite, which could have oxidizing properties per se or oxidizing agent could be hydrolizable into oxidizing moiety. The oxidizing agent is formulated in a sustained-release polymeric drug delivery system or liposomal preparation. The chlorite/peroxide preparations when applied to treat dermal disorders, have a broad anti-microbial activity, including activity against gram positive, and gram negative bacteria, yeasts and fungi. See column 8, lines 10-23. The formulations can be in the form of, gels, ointments, creams, sprays, etc. The formulations can contain salts such as sodium chloride. See column 9, lines 43-45, FORMULA 1. The gel formulations may containing drug delivery vehicles like biocompatible polymers such as hydroxypropyl methylcellulose, hydroxyethylcellulose, acrylic polymers, polyvinylpyrolidone, etc. which control the release of the oxidizing agent. A wide variety of flexible, spreadable, and conformable polymers are disclosed. See column 10, lines 10-67.

Thus, Karagoezian anticipates claims 1-5, 9-11, 26-30, 34-37, 39-40, 57-61, 65-67, and 69-70.

Claims 1-11, 15-37, 39-40, 44-67, 69-70, 74-85, 150-151, 155-156, and 158-163 are rejected under 35 U.S.C. 102(e) as being anticipated by Green (US 6,592,890, PTO-892).

The instant claims are directed toward a Pharmaceutical composition comprising an oxidizing agent being entrapped in a silicone polymer, a method of treating a skin or mucosal membrane ailment using said composition, and method of preparing a pharmaceutical composition

Green discloses a wound dressing composition having an anti-infective activity for treating skin ailments caused by microorganisms such as bacteria, comprising a sheet comprising a crosslinked polymer matrix, and oxidant generating formulation within or on the polymer matrix. Green also discloses that the oxidant generating formulation is stable at least until contacted by a substrate, such as glucose, which is permeable into the polymeric matrix from the patients body fluid. See column 4, lines 38-54; column 20, TABLE 3. It is also disclosed that the wound dressing can be a single sheet having the oxidant generating formulation, or plurality of staked sheets, having the same composition. See column 4, lines 56-65. The conformable, flexible, and spreadable polymers such as cross-linked polymers of polyacrylamide, polyurea, polyurethane, polyvinylchloride, polyesters, polymethyl methacrylate, polytetrafluorethylene, elastomeric organosilicon polymers etc., and combination thereof are disclosed. Hydrophobic polymers (elastomers) include such as medical grade Low Consistency Silicone elastomers such as NuSil MED-815, High consistency Silicone Elastomers suitable for extrusion such as NuSil MED-

4550, as well as thermoplastic and room temperature vulcanization (RTV) silicone polymers. See column 11, lines 43-61. Suitable anti-infective oxidizing agents disclosed are elemental iodine, hydrogen peroxide, hypohalites, hypothiocyanite etc. See column 14, lines 61-66. It is also disclosed that oxidizing agents hypohalites such as hypochlorites is formed upon wetting of the polymer in a body fluid. See column 15, lines 60-65. A 4 % by weight of oxidizing agent iodate in the composition is also disclosed. See column 21, lines 45-47. The data for anti-bacterial activity of oxidizing agent iodate in combination with iodide encapsulated Silicone patches is shown in column 19, TABLE 2. It is also disclosed that using a bilayer technique formulations of iodide and oxidizing agents of iodide can be encapsulated in a thin polymer comprising the upper layer, and this allows the sustained release of iodide and oxidizing agent over extended period of time. See column 10, lines 8-15. It further disclosed that the sponge like hydrogel composition containing oxidizing agent encapsulated in polymer can be farbricated into various shapes such as rolls, sheets etc. See column 12, lines 60-66. Disc shaped silicone devices containing the oxidizing agents in combination with NaCl were also prepared. See column 19, lines 20-23.

Green further teaches a method of preparing a pharmaceutical composition. Green teaches that finely ground oxidizing agent iodate and iodide were mixed into silicone elastomer and then the polymer was allowed to cure with dibutyl tin dilaurate catalyst. See column 17, EXAMPLE 1; column 19, lines 20-25; and column 21, EXAMPLE 3. A bilayer technique is also disclosed wherein the

formulations of iodide and iodate, or other oxidizing agents of iodide are encapsulated in a thin polymer of polyurethane or silicone comprising the upper layer, and combined with another film of polyurethane or silicone containing polymer. See column 10, lines 7-24.

Thus, Green anticipates claims 1-11, 15-37, 39-40, 44-67, 69-70, 74-85, 150-151, 155-156, and 158-163.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41-43, and 71-73 are rejected under 35 U.S.C. 103 as being unpatentable over Green (US 6,592,890) as applied to claims 1-11, 15-37, 39-40, 44-67, 69-70, 74-85, 150-151, 155-156, and 158-163 in view of Boddie at al. (J. Dairy Sci. 79, 1996, 1683-1688).

Green is as discussed above (see page 10 of this Office action).

Green does not teach the use of the oxidizing agent comprising chlorinated isocyanurate entrapped in the polymer, and a method of treating skin ailment using the specific oxidizing agent, comprising chlorinated isocyanurate entrapped in the polymer.

Boddie et al. disclose the use of oxidizing agent comprising a chlorinated isocyanurate in a similar formulation and a method of treating teat skin infected

by microorganisms using said formulation. Boddie teaches that teat dip formulations containing an oxidizing agent hypochlorous acid (a source of free chlorine), liberated from sodium dichloroisocyanurate in water by hydrolysis, were effective against bacteria such as *Staphylococcus aureus* and *Streptococcus agalactiae* IMI. See page 1683, column 2, lines 24-29.

It would have been obvious to a person of ordinary skill in the art at the time of invention to use an oxidizing agent comprising a chlorinated isocyanurate such as trichloroisocyanuarate or sodium dichlorocyanurate in the wound dressing composition of Green for treating skin ailment because Boddie teaches teat dip formulation containing sodium isocyanurate for treating skin infections caused by bacteria.

One of ordinary skill in the art would have been motivated to use oxidizing agent comprising sodium isocyanurate entrapped in the polymer with the expectation of obtaining a pharmaceutical composition that allows the sustained release of oxidizing agent over extended period of time as instantly claimed for the treatment of skin ailment caused by bacteria.

Therefore, claims 41-43, 71-73 are seen to be clearly obvious over the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on 8 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni
Patent Examiner
Art Unit : 1617

4/18/05

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